

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Ulf TILSTAM et al.

Examiner: Elli PESELEV

Serial No.: 09/471,040

Group Art Unit: 1623

Filed: December 23, 1999

Title: PROCESS FOR THE PRODUCTION OF FLUDARABINE-PHOSPHATE LITHIUM, SODIUM, POTASSIUM, CALCIUM AND MAGNESIUM SALTS AND PURIFICATION PROCESS FOR THE PRODUCTION OF FLUDARABINE-PHOSPHATE AND FLUDARABINE-PHOSPHATE WITH A PURITY OF AT LEAST 99.5%

**REPLY**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The examiner continues to reiterate that the combination of Blumbergs and Butler renders the claimed subject matter obvious. This is incorrect.

Applicants stand by their position as stated in the response of October 31, 2007.

The examiner has not responded in any way to the substance of that reply. The PTO continues simply to restate its same position without regard to applicant's rebuttal.

The examiner's position as stated in the paragraph bridging pages 3 and 4 of the office action seems to be implying that applicants are required to demonstrate an unexpected advantage for the claimed 99.5 or greater purity compound in comparison to the prior art product of lower purity. Whereas this may be one way to demonstrate the patentability of the claimed subject matter, it is not the only way. Again, the examiner is referred to applicant's reply which quoted a relevant passage from the recent Aventis decision in the Federal Circuit which states that a claimed composition in purified form can be established as patentable where "the state of the art may be such that discovering how to perform the purification is an invention of patentable weight

in itself.” This is precisely the case at issue. Everything of record supports the fact that the claimed compound cannot be obtained in the claimed purity by any conventional technique.

Applicants have previously explained why the data previously of record already firmly established the fact that it was not reasonable to expect that the Butler process would be able to purify the claimed compound to the requisite degree. Since the examiner seems for unexplained reasons not to have considered this argument, in an effort to further expedite this proceeding, applicants have now reproduced the Butler process as applied to the claimed compound. As fully expected, the process and reasonable variations thereof designed to enhance the purity of the final product, failed to produce the claimed compound in the requisite purity. See the accompany Sholz declaration.

The rejection should be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Anthony J. Zelano/

Anthony J. Zelano, Reg. No. 27,969

Attorney for Applicant(s)

MILLEN, WHITE, ZELANO

& BRANIGAN, P.C.

Arlington Courthouse Plaza 1, Suite 1400

2200 Clarendon Boulevard

Arlington, Virginia 22201

Telephone: (703) 243-6333

Facsimile: (703) 243-6410

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